IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	LaPointe, *et al.*		
Assignee:	CYTYC Corporation		
Filing Date:	January 11, 2002	Examiner:	Starks, Wilbert
Serial No.:	10/043,356	Group Art Unit:	2129
Title:	METHOD FOR SELECTING MEDICAL AND BIOCHEMICALDIAGNOSTIC TESTS USING NEURAL NETWORK-RELATED APPLICATIONS		

COMMISSIONER FOR PATENTS
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February 20, 2008

RESPONSE TO OFFICE ACTION

Dear Sir:

In response to the Office action of September 20, 2007 ("Office Action"), the Applicants respectfully requests reexamination and reconsideration of the above-identified application in view of the following remarks.

Remarks begin on page 2 of this paper.

REMARKS

Status of the Claims

Claims 1-6 were originally pending in the application. Claims 1-6 have been rejected.

Rejection of Claims 1-6 Under 35 U.S.C. 102(b)

The Examiner has rejected Claims 1-6 U.S.C. 102(b) as being anticipated by Hutcheson, *et al.* (USP 5,465,308). Specifically, the Examiner argues that Claim 1's recitation of "a computer system comprising a neural network or plurality thereof trained for diagnosing endometriosis" is anticipated by Hutcheson, *et al.* at column 28 lines 61-67 and column 29 lines 1-16 where it is recited:

> "Any time varying analog signal input compatible with well known analog to digital conversion boards compatible with computers can be processed as described herein. Representative signals might include seismic traces, radar signals, voice, medical diagnostic signals such as EKG, EEG etc., and any other sensor signal. Any signal which has a periodicity or is bounded and limited in its content and which can be digitized so as to be stored in computer memory may be presented to the system with Input Feature Vectors generated by the mechanisms previously described, and operated on using the training and recognition techniques set forth herein. Since the system uses supervised learning techniques, the choice of system desired outputs can range from the identity of the object, to "good/bad" or "pass/fail" answers, independent of the type of input. The Feature Template mechanism guarantees maximal separability between objects in the same class, the Feature Vector extraction mechanism the optimal Input Feature Vector, and the recognition mechanism the closest fit to the desired result, with application dependent analysis of the resulting confidence levels. Thus, for the different applications cited, no system reprogramming is required for different applications."

Applicants respectfully traverse this rejection.

To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons or ordinary skill in the field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F 3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)) Hutcheson, *et al.* does not anticipate the presently claimed invention for two reasons. First, Hutcheson, *et al.* does not disclose all of the limitations of the claims. Second, Hutcheson, *et al.* does not enable the present claims.

Hutcheson, *et al.* does not disclose all of the limitations of the claims

Hutcheson, *et al.* cannot anticipate any of the pending claims because it does not disclose all of the limitations of the pending claims. Hutcheson, *et al.* teaches a pattern recognition system which utilizes a neural network to recognize two dimensional input images which are sufficiently similar to a database of previously stored two dimensional images (abstract).

Claim 1 of the present invention recites a computer system, comprising a neural network for diagnosing endometriosis. Hutcheson, *et al.* does not teach or suggest a computer system trained for the diagnosis of endometriosis. In fact, there is no mention anywhere in Hutcheson, *et al.* of a computer system trained for the diagnosis or any disease.

Claim 2 of the present invention recites a method for diagnosing endometriosis in a subject, comprising: querying and examining the patient to assess the answers to at least three of the following questions: past history of endometriosis, number of births, dysmenorrhea, age, pelvic pain, history of pelvic surgery, smoking and if yes, the number of packs/day, medication history, number of pregnancies, number of abortions, abnormal PAP smear/dysplasia, pregnancy hyperplasia, genital warts and diabetes; and based upon the results of the answers determining whether the patient has

endometriosis. Hutcheson, *et al.* does not teach or suggest a method for diagnosing endometriosis in a subject. Hutcheson, *et al.* also does not teach or suggest the querying and examining a patient to assess answers to any questions, let alone the specific questions defined in Claim 2.

Claim 3 of the present invention recites a computer system, comprising a neural network trained for assessing the risk of delivery within a selected time period, wherein the time period is within seven or fourteen days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject or the time period is prior to thirty five weeks of gestation. Hutcheson, *et al.* does not teach or suggest a neural network trained for assessing the risk of delivery within a selected time period. Hutcheson, *et al.* also does not teach or suggest a time period within seven or fourteen days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject.

Claims 4, 5, and 6 of the present invention which contain all the limitations of Claim 3 recite further limitations of the time period for assessing the risk of delivery. Hutcheson, *et al.* does not teach or suggest a neural network trained for assessing the risk of delivery within any time period, let alone the time periods recited in claims 4, 5 and 6.

Accordingly, because Hutcheson, *et al.* does not teach or suggest a computer system, comprising a neural network for diagnosing endometriosis, claims 1 and 2 cannot be anticipated by Hutcheson, *et al.* Because Hutcheson, *et al.* does not teach or suggest a computer system, comprising a neural network trained for assessing the risk of delivery within a selected time period, claim 3 cannot be anticipated by Hutcheson, *et al.* Claims 4, 5, and 6 are not anticipated by Hutcheson, *et al.* at least by virtue of their dependency from claim 3. In light of the foregoing, it is clear that the Examiner has not established a case of *prima facie* anticipation. Withdrawal of the rejection of claims 1-6 under U.S.C. 102(b) is respectfully requested.

Hutcheson, *et al.* cannot anticipate the claims because it is not enabling

As noted previously, to establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations.

For a prior art reference to be enabling, the description must enable a person with ordinary skill in the art not only to comprehend the invention but also to make it (*Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d at 665, 231 USPQ 649, 653 (Fed Cir. 1986), *cert denied*, 480 U.S. 933 (1987)). The Federal Circuit has further stated that: "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." (*Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ2d 1001, 1010 (Fed Cir. 1991)) (emphasis added).

The Examiner argues that Claim 1's recitation of "a computer system comprising a neural network or plurality thereof trained for diagnosing endometriosis" is anticipated by Hutcheson, *et al.* at column 28 lines 61-67 and column 29 lines 1-16, specifically holding the words "**medical diagnostic signals**", "**and any other sensor signal**", "**any signal**", "**may be presented to the system**", and "**supervised learning techniques**". Aside from highlighting these words from the text of Hutcheson, *et al.*, the Examiner has made no other argument as to how or why these phrases are relevant. As mentioned previously, Hutcheson, *et al.* teaches a pattern recognition system which utilizes a neural network to recognize two dimensional input images, in particular, photographic images. There is simply no teaching or suggestion in Hutcheson, *et al.* of a computer system trained for the diagnosis of endometriosis as recited in independent Claim 1; the querying and examining a patient to assess answers to any questions, let alone the specific questions as recited in independent Claim 2; a time period within seven or fourteen days of performing a biochemical test to measure fetal fibronectin in a sample from a pregnant subject as recited in independent Claim 3, and the

further limitations of the time period for assessing the risk of delivery as recited in dependent claims 4, 5, and 6. Simply put, there is no teaching or suggestion in Hutcheson, *et al* of a system for diagnosing any type of disease. Without such a teaching, there are potentially indefinite numbers of input "signals" suggested by Hutcheson, *et al*, none of which have been described as being desirable for the diagnosis of endometriosis or for assessing the risk of delivery.

If the Examiner is arguing that the limitations recited in Claims 1-6 fall under any of the general categories of terms highlighted by the Examiner such as "**medical diagnostic signals**", "**and any other sensor signal**", "**any signal**", "**may be presented to the system**", and "**supervised learning techniques**", then it is clear that Hutcheson, *et al.* does not satisfied the requirement of providing description to enable a person with ordinary skill in the art not only to comprehend the invention but also to make it. As can be appreciated from the forgoing, any assertion that Hutcheson, *et al.* enables a person with ordinary skill in the art to practice a computer system, comprising a neural network for diagnosing endometriosis or for assessing the risk of delivery is incorrect.

For the reasons outline above, it is Applicants' position that Hutcheson, *et al.* does not enable the present claims. "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every limitation of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000) (emphasis added). Hutcheson, *et al.* does not meet this standard.

In light of the foregoing, it is clear that the Examiner has not established a case of *prima facie* anticipation. Withdrawal of the rejection of claims 1-6 under U.S.C. 102(b) is respectfully requested.

CONCLUSION

In view of the above arguments, the Applicants believe the pending application is in condition for allowance. A two month extension is hereby requested. It is believed that no additional fees are required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicants, the Examiner is invited to contact Applicants' attorney at the number noted below

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Respectfully submitted,

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